Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2921033

August 18, 2000

Susan A. Louie, President
Alfred Louie, Inc.
4501 Shepard Street
Bakersfield, CA 93309

WARNING LETTER

Dear Mrs. Louie:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 4501 Shepard Street, Bakersfield, California on June 26 and 28, 2000.

The inspection revealed that you have failed to adopt effective preventive controls to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and to assure that sprouts are not adulterated under the food safety provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, your sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they have been prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your sprouting facility.

Furthermore, the inspection revealed insanitary practices and conditions which cause all foods in your firm to be adulterated within the meaning of Section 402(a)(4) of the Act, because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth.

The following is a list of the insanitary practices, conditions, and findings observed by the FDA investigator:

BEAN SPROUT PROCESSING

1. FAILURE TO PERFORM MICROBIAL TESTING OF SPENT IRRIGATION WATER: A copy of the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is enclosed. This guidance document is intended to assist sprout manufacturers in implementing one of the

principal recommendations in the guidance document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds," which is also enclosed.

FDA currently recommends the treatment of pre-washed seed with 2% (20,000 ppm available chlorine) calcium hypochlorite solution for 15 minutes at room temperature with continuous agitation. The ratio of five (5) pounds of seed in one gallon 2% calcium hypochlorite solution is recommended. See enclosed EPA Reg. #1258-427.

2. USE OF UNWASHED/UNSANITIZED WOODEN CRATES: Unwashed/unsanitized wooden crates, which had previously been used to hold fresh produce, were used to hold open bags of sprouts and were stacked one on top of another. The wooden crates had previously been on unwashed/unsantized wooden pallets or on the production room floor in that filth or pathogens from the pallets or floor may likely contaminate the sprouts.

3. EMPLOYEE PRACTICES: An employee was observed handling wooden crates and then handling sprouts without washing or sanitizing his hands.

4. WATER HOSE: A water hose was observed immersed in a bucket of mung beans to rinse off the disinfecting solution. The same water hose was observed lying on the concrete floor.

5. AUTOMATIC IRRIGATOR: The automatic irrigator and rail are rusted. There are also rust particles on the top and sides of the water hose attached to the automatic irrigator.

NOODLE PROCESSING

1. THE SCALE IS USED FOR BOTH WEIGHING NOODLES AND WEIGHING FRESH VEGETABLES: There is no cleaning or sanitation of the scale after weighing fresh vegetables and before weighing noodles. There is a potential for cross-contamination of dirt or filth from the fresh vegetables to the noodles.

2. WORN, FRAYED DUCT TAPE WAS OBSERVED ON THE EDGE OF THE DOUGH BASKET ON THE KNEADING MACHINE

BUILDING

1. ROLL-UP DOORS HAVE LARGE GAPS WHICH COULD ALLOW ENTRY OF PESTS: The four roll-up doors at the loading dock and the roll-up door in the west-end receiving area all have gaps of ¼" to 1" on the sides and tops. The sides and tops of all doors are not sealed.

2. DOORS ON EAST AND WEST SIDES HAVE ¼" GAPS WHICH COULD ALLOW ENTRY OF PESTS.

At the conclusion of the inspection, the insanitary practices and conditions and failure to adopt effective preventive controls for sprout processing were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. FDA will consider enforcement actions against any party who does not have effective preventive controls in place with respect to sprouts, in particular, effective microbial testing.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,

Mary Woleske

Mary H. Woleske
Acting District Director
San Francisco District

Enclosures:

Guidance for Industry Document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Guidance for Industry Document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds"

EPA REG. #1258-427

Form FDA 483